

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates to:
All Actions

**DEFENDANTS' MEMORANDUM
IN SUPPORT OF MOTION TO
TAKE DISCOVERY
CONCERNING NEW AUGUSTINE
ARTICLE RELIED UPON BY
PLAINTIFFS AND THEIR
EXPERTS**

Last month, Dr. Scott Augustine published a new article that reports on “studies” at three hospitals, claiming to demonstrate that transitioning from the 3M Bair Hugger system to Augustine’s HotDog decreased the risk of joint infections. Plaintiffs rushed to embrace Augustine’s publication, putting it in the hands of their general-causation experts as further “support” for their opinions, and employing it in Plaintiffs’ cross-examination of 3M’s experts. Plaintiffs’ lead expert, Dr. Samet, even testified that Augustine’s new publication *by itself* provides sufficient foundation for his opinions. For all intents and purposes, Dr. Augustine has become Plaintiffs’ sur-rebuttal expert.

3M took extensive discovery during the general causation fact discovery period concerning the data and conclusions of the other Augustine-sponsored publications relied upon by Plaintiffs. 3M should be allowed the same for Augustine’s new publication, and should be allowed to do so before it proceeds with completion of Dr. Augustine’s deposition (which it deferred after learning of Augustine’s new publication). 3M therefore requests the Court’s leave to take discovery of the three hospitals relied upon by Dr.

Augustine, as well as related discovery of Dr. Augustine and his entities. 3M should be allowed to obtain the underlying data relied upon by Augustine, the study protocols, and communications about the data, and should be permitted to depose the hospitals. Ridgeview Medical Center – which 3M knows to be of the three – has already stated that they never participated in any “study” and that their data do not show what Augustine and Plaintiffs claim. One suspects the other hospitals will tell the same story.

ARGUMENT

A. Good Cause Exists to Take Discovery of the Hospitals Referenced in Augustine’s Publication.

Augustine’s article, published in a pay-to-publish Italian internet journal, reports on the results of “studies” he claims were conducted at three hospitals that switched from the Bair Hugger system to Augustine’s HotDog. *See* Scott D. Augustine, *Forced-air warming discontinued: periprosthetic joint infection rates drop*, Orthopedic Reviews 2017; vol. 9:6998, 39 (2017) (Declaration of Monica L. Davies (“Davies Decl.”), Ex. 1). According to Augustine, each study “shares a study design similar to the McGovern study” (the primary study relied upon by Plaintiffs and their experts) and “corroborates the findings of the McGovern study.” *Id.* at 40-41.

Following the publication, Plaintiffs’ counsel immediately provided Augustine’s article to their experts. Plaintiff’s lead expert, Dr. Samet, disclosed at his deposition that he is relying on the article, and indeed that Augustine’s article provides sufficient foundation by itself for his general-causation opinion. *See* Davies Decl., Ex. 2, Deposition of Jonathan Samet, M.D. at 30:4-35:13 (testifying that he regards Augustine’s article as

“another piece of observational evidence that provides an estimate of risk of deep joint infection associated with the Bair Hugger device versus the comparison”); *id.* at 165:13-24 (if McGovern was taken out of consideration, Dr. Samet would point to Augustine’s study as support for his opinions).

Moreover, over the last two weeks, Plaintiffs repeatedly used Augustine’s new publication in cross-examining 3M’s experts. Last Thursday, Yale epidemiologist Dr. Jonathan Borak was questioned about Augustine’s article by Plaintiffs. *See* Davies Decl., Ex. 3, Deposition of Jonathan Borak at 203:4-11. Looking at the paper and the data provided by Ridgeview in earlier discovery, Borak raised serious questions about the credibility of the article:

It doesn’t seem to follow its protocol, it seems to have cherry picked data. . . . There are data from Ridgeview Medical Center that were apparently provided under whatever process legally which shows a compilation of knee and hip surgeries and infectious rates for four years, 2006, 2007, 2008, 2009.

Looking at the recent Augustine paper, it appears that he only dealt with the knees, not the hips, nor the two combined, that he compared 2006 knees to 2008 and 2009 knees, which was not at all what he said would be the protocol, which was a two-month or three-month washout period, and that he selectively – selectively excluded the 2007 data.

And so it doesn’t look to me as though the Augustine paper is based on legitimate data, it looks as though – well “legitimate,” real but selected in a way to influence the appearance of an outcome.

Id. at 203:12-204:5; *see also* Davies Decl., Ex. 4, Deposition of Theodore R. Holford at 318:14-326:7 (discussing details that are missing from the Augustine report, noting “[t]he list of things that are not here . . . is pretty remarkable”).

Plaintiffs and their experts' bear hug of Augustine's new publication necessitates further discovery. This is further underscored by statements from Ridgeview, one of the hospitals addressed in Augustine's publication. While he declined to answer a number of questions concerning his then-forthcoming publication, Dr. Augustine did identify Ridgeview as one of the three hospitals. Ridgeview has, of course, insisted to 3M and this Court that it did not participate in any "study" with Augustine:

Ridgeview Medical Center did not participate in a study with Scott Augustine or any entity owned by Scott Augustine, including but not limited to, Augustine Temperature Management or Augustine BioMedical Design.

The study never came to fruition between Ridgeview Medical Center and Scott Augustine, or any entity owned in whole or in part by him.

Dkt. No. 445, Aff. Of Julie Hauser at ¶¶ 31-32 (emphasis added); *see also* Dkt. No. 444, Ridgeview Opp. to Mot. to Remove Confidential Designation, at 2.

As alluded to by Dr. Borak, Ridgeview's previously produced documents further confirm that the representations made by Augustine are false, and that Ridgeview's reduced infection rates were not caused by its switch to the HotDog:

- "[T]here is ***no data to support a direct correlation*** to [the HotDog patient warming system] and our reduced infection rates." Davies Decl., Ex. 5 (emphasis added).
- "There is ***no supportive data*** that we have or that the Surgeons ***would support the Hot Dog as the connection to reduced infection rates***. Our rates are lower based on the work of a number of folks and a number of different initiatives. No direct correlation to that product and I have been very clear about it with them." *Id.* (emphasis added).

It is remarkable that Plaintiffs and their experts would embrace Augustine's article in light of these statements by Ridgeview – but, of course, if Plaintiffs did not embrace Augustine and the “studies” he has sponsored, they would have nothing left.

In sum, 3M should be permitted to take discovery from the three hospitals involved, including updating its discovery from Ridgeview and deposing their corporate representative. 3M will be prejudiced in its defense if it is not permitted to take the same kind of discovery it was previously permitted to take concerning other studies relied upon by Plaintiffs – to obtain, review, and analyze the data reported by Augustine, as well as any other protocols these hospitals may have had in place that could affect infection rates.

B. Good Cause Exists to Allow 3M to Further Extend the Continued Deposition of Augustine.

On May 25, the Court granted 3M's request for an additional four hours to depose Augustine. At the time, however, Augustine's publication had not been released and it was unclear that it ever was going to be published. 3M did not know – and frankly, did not expect – that Dr. Augustine would continue to rely on data from Ridgeview given Ridgeview's public disagreement with his claims. More importantly, Augustine's “study” had not, at that point, been embraced by Plaintiffs or their experts. Because the study is now an integral part of Plaintiffs' general-causation case, 3M should be allowed additional time to fully examine Augustine about his publication and support for it, in addition to the other topics yet to be explored. 3M thus requests an additional five hours (for a total of nine additional hours), as well as an opportunity to serve a subpoena on Augustine, to obtain his communications with journals regarding his recent publication.

CONCLUSION

For all of the foregoing reasons, 3M respectfully request that the Court (1) grant leave to take written and deposition discovery from the hospitals discussed in Augustine's July 2017 publication, including updating its discovery to Ridgeview Medical Center; (2) allow 3M a total of nine additional hours (in lieu of the four previously granted) to complete Augustine's deposition; and (3) allow 3M to seek additional documents from Augustine and his various entities concerning the publication.

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Respectfully submitted,

s/Monica L. Davies

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